# 510(k) SUMMARY Amendia's Apollo Suture Anchor and Titan Screws

Date:

September 11, 2013

Contact:

Daniel Lanois, General Manager

**Trade Name:** 

**Apollo Suture Anchor System and Titan Screws** 

**Common Name:** 

Screw, Fixation, Bone

Product Class:

Class II

Classification:

21 CFR §888.3040 – Smooth or threaded metallic bone fixation

fastener

**Product Code:** 

MBI

Panel Code:

87

#### Name/Address of Sponsor

Amendia, LLC 1755 West Oak Pkwy Marietta, GA 30062 770-575-5200

#### Purpose:

The purpose of this submission is clearance of the Apollo Suture Anchor System and Titan Screws as a new medical device that is substantially equivalent to the predicate device.

# **Device Description**

#### **Apollo Family**

The Apollo Medial Suture Anchor, Lateral Anchor, and Suture Tac Delivery Systems are delivery systems for anchors for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. These anchors consist of cannulated anchors with integrated suture attachment or separate suture punch eyelet. The Anchors are provided loaded on individual inserters with and without integrated sutures, sterile, for single use only.

#### **Titan Family**

The Titan Interference and Tenodesis Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are provided sterile, for single use only.

Screw and anchor implants are made from either a titanium alloy (6Al4V) per ASTM F136, or PEEK (Zeniva ZA-500) per ASTM F2026 from Solvay Advanced Polymers.

#### **Predicate Device**

The Apollo Suture Anchor System and Titan Screws are substantially equivalent to Smith and Nephew Biosure PK Interference Screw (K083635), the DePuy Mitek Healix PEEK Anchor (K120449), the Biomet PEEK Allthread Knotless Suture Anchor and Hitch PEEK Anchor (K071569 and K060693), and the Arthrex Tenodesis Screw (K041356).

#### Intended Use / Indications for Use

The Apollo Suture Anchors and Titan Screws are indicated for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are intended for use in the following procedures:

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Indications – Apollo Medial Suture Anchor	Indications – Apollo Lateral Anchor
The Apollo Medial Suture Anchor is intended for:	The Apollo Lateral Anchor is indicated for:
Shoulder	Shoulder
Rotator Cuff Repair	Rotator Cuff Repair
☐ Bankart Repair	Bankart Repair
SLAP Lesion Repair .	SLAP lesion Repair
☐ Biceps Tenodesis	☐ Biceps Tenodesis
AcormicClavicular Separation Repair	☐ AcormicClavicular Separation Repair
☐ Deltoid Repair	☐ Deltoid Repair
☐ Capisular Shift or Capsulolabral Reconstruction	☐ Capisular Shift or Capsulolabral Reconstruction
Foot/Ankle	Wrist/Hand
☐ Lateral Stabilization	☐ Scapholunate Ligament Reconstruction
☐ Medial Stabilization	☐ Ulnar/Radial Collateral Ligament Reconstruction
☐ Achilles Tendon Repair	
	Foot/Ankle
Knee	☐ Lateral Stabilization
☐ Medial Collateral Ligament Repair	Medial Stabilization
☐ Lateral Collateral Ligament Repair	Achilles Tendon Repair/Reconstruction
Posterior Oblige Ligament Repair	☐ Hallux Valgus Reconstruction
☐ Illiotibial Band Tenodesis	☐ Midand Forefoot Reconstruction
Elbow	Elbow
☐ Biceps Tendon Reattachment	☐ Biceps Tendon Reconstruction
Ulnar or Radial Collateral Ligament Reconstruction	Ulnar or Radial Collateral Ligament Reconstruction
Hip	☐ Lateral Epicondylitis Repai(PEEK Anchor Only)
Capsular Repair	
Acetabular Labral Repair	Knee
	☐ Medial Collateral Ligament Repair
	☐ Lateral Collateral Ligament Rpair
	☐ Posterior Oblique Ligament Repair
	☐ Joint Capsule Closure
	☐ Iliotibia! Band Tenodesis
	☐ Patellar Ligament/Tendon Repair
Indications – Apollo Labral Suture Tac Shoulder	
Rotator Cuff Repair	
Bankart Repair	
SLAP Lesion Repair	

# K133036

☐ Biceps Tenodesis	
AcormieClavicular Separation Repair	
☐ Deltoid Repair	
☐ Capisular Shift or Capsulolabral Reconstruction	
Wrist	
Scapholunate Ligament Reconstruction	
Elbow	•
☐ Biceps Tendon Reattachment	•
Ulnar or Radial Collateral Ligament Reonstruction	
402-	
Hip	
Capsular Repair	
Acetabular Labral Repair	
Knee	
☐ Extracapsular Repair	
Medial Collateral Ligament Repair	
☐ lateral Collateral Ligament Repair	•
Posterior Oblique Ligament Repair	•
Joint Capsule Closure	,
☐ Iliotibial Band Tenodesis Reconstruction	
Patellar Ligament/Tendon Repair	
☐ Vastus Mediais Obliquus Muscle Advancement	
Indications –Interference Screws	Indications –Tenodesis Screws
The Titan Interference Screws are indicated for the	The Titan Tenodesis Screws are intended to be used for fixation
reattachment of ligament, tendon, soft tissue, or bone to bone	of tissue, including ligament or tendon to bone, or a
during cruciate ligament reconstruction surgeries of the knee.	bone/tendon to bone. See below for specific indications.
All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following	The Tenodesis Screws are intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue).
procedures:	See below for specific indications.
Knee	Shoulder
☐ ACL repairs	☐ Capsular stabilization
☐ PCLrepairs	o Bankart repair
Extracapsular repairs	o Anterior shoulder instability
o Medial collateral ligament	o SLAP lesion repairs .
o Lateral collateral ligament	o Capsular shift of capsulolabral reconstructions
o Posterior oblique ligament	Acromiocla gular separation repairs
Patellar realignment and tendon repairs	☐ Deltoid repairs
o Vastus medialis oliquous advancement	Rotator cuff tear repairs
☐ Iliotibial band tenodesis	☐ Biceps tenodesis
Chavilden	
Shoulder  Capsular stabilization	Foot and Ankle
o Bankart repair	☐ Hallux valgus reconstruction
Anterior shoulder instability	☐ Medial stabilization
o SLAP lesion repairs	☐ Lateral stabilization
o Capsular shift of capsulolabral reconstructions	Achilles Tendon Repair
Acromioclavicular separationepairs	☐ Midfoot reconstructions
Deltoid repairs	☐ Metatarsal ligament repair
Rotator cuff tear repairs	☐ Bunionectomy
<del>-</del>	☐ Flexor Hullucis Longus for Achilles Tendon reconstruction
☐ Biceps tenodesis	Tendon transfers in the foot and ankle
Foot and Ankle	
Hallux valgus repairs	
☐ Medial or lateral instability repairs/reconstructions	Knee
Achilles tendon repairs/reconstructions	☐ Medial Collateral Ligament Repair
Midfoot reconstructions	Lateral Collateral Ligament Repair
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☐ Metatarsal ligament/tendon repairs/reconstructions	☐ Patellar Tendon Repair
Bunionectomy	Posterior Oblique Ligament Repair
☐ Flexor Hullucis Longus	☐ Illiotibial Band Tenodesis
☐ Tendon transfers	☐ Posterior Cruciate Ligament Repair
Elbow, Wrist, and Hand	Elbow
☐ Biceps tendon reattachment	☐ Biceps tendon reattachment
☐ Ulnar or radial collateral ligament reconstructions	☐ Ulnar or radial collateral ligament reconstruction
☐ Lateral epicondylitis repair	
☐ Scapholunate ligament reconstruction	Wrist and Hand
Tendon transfers	Scapholunate Ligament Reconstruction
[ ] Tendon (tansiers	☐ Unar Collateral Ligament Reconstruction
	☐ Radial Collateral Ligament Reconstruction
	☐ Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty)
	☐ Carpal Ligament Reconstructions and repairs
	☐ Tendon transfer in the hand/wrist
	☐ Lateral Epicondylitis repair
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#### Performance Data:

Performance testing included axial pullout, axial push out, insertion torque, and torque to failure tests per ASTM F543-07. Side-by-side testing to predicate devices was completed with test results demonstrating that the Apollo Suture Anchor System and Titan Screws are substantially equivalent to the predicate devices.

# Summary:

The Apollo Suture Anchor System and Titan Screws are substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Mechanism of action
- Dimensions

There are no significant differences in technological characteristics compared to the predicate device that would raise any new types of safety or efficacy issues.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

#### March 6, 2014

Amendia, LLC % Dr. Richard Jansen, Pharm. D. President Silver Pine Consulting 13540 Guild Ave. Apple Valley, Minnesota 55124

Re: K133036

Trade/Device Name: Apollo Suture Anchor System and Titan Screws

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II Product Code: MBI

Dated: January 17, 2014 Received: February 14, 2014

Dear Dr. Jansen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

#### Page 2 - Dr. Richard Jansen

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincen Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

#### **Indications for Use Statement**

510(k) Number (if known): K133036

Device Name: Apollo Suture Anchor System and Titan Screws

# Intended Use / Indications for Use

The Apollo Suture Anchors and Titan Screws are indicated for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are intended for use in the following procedures:

Indications – Apollo Medial Suture Anchor	Indications – Apolio Lateral Anchor
The Apollo Medial Suture Anchor is intended for:	The Apollo Lateral Anchor is indicated for:
Shoulder	Shoulder
☐ Rotator Cuff Repair	Rotator Cuff Repair
☐ Bankart Repair	☐ Bankart Repair
SLAP Lesion Repair	SLAP Lesion Repair
☐ Biceps Tenodesis	☐ Biceps Tenodesis
AcormieClavicular Separation Repair	AcormieClavicular Separation Repair
Deltoid Repair	Deltoid Repair
Capisular Shift or Capsulolabral Reconstruction	Capisular Shift or Capsulolabral Reconstruction
Foot/Ankle	Wrist/Hand
☐ lateral Stabilization	Scapholunate Ligament Reconstruction
Medial Stabilizatio	Ulnar/Radial Collateral Ligament Reconstruction
Achilles Tendon Repair	Foot/Ankle
Knee	□ Lateral Stabilization
Medial Collateral Ligament Repair	☐ Medial Stabilizatio
lateral Collateral Ligament Repair	Achilles Tendon Repair/Reconstruction
Posterior Oblique Ligament Repair	Hallux Valeus Reconstruction
☐ Illiotibial Band Tenodesis	Midand Forefoot Reconstruction
Elbow	Elbow
Biceps Tendon Reattachment	Biceps Tendon Reconstruction
Ulnar or Radial Collateral Ligament Reconstruction	Ulnar or Radia) Collateral Ligament Reconstruction
Hio	Lateral Epicondylitis Repai(PEEK Anchor Only)
Caosular Repair	Knee
Capsular Repair	Medial Collateral Ligament Repair
☐ Acetaonat rapiat keban	Lateral Collateral Ligament Repair
	Posterior Oblique Ligament Repair
1	Joint Capsule Closure
	☐ Biotibial Band Tenodesis
	Patellar Ligament/Tendon Repair
	1 a (chai Danich) Ichoon Repail
Indications – Apollo Labral Suture Tac Shoulder	
Rotator Ouff Repair	
☐ Bankart Repair	
SLAP Lesion Repair	
Biceps Tenodesis	
☐ AcormicClavicular Separation Repair	
☐ Deltoid Repair	
☐ Capisular Shift or Capsulolabral Reconstruction	
Wrist	
☐ Scapholunate Ligament Reconstruction	
Elbow	
Bice Tendon Reattachment	
Umar or Radial Collateral Ligament Reconstruction	
Hip	
Capsular Repair	
Acetabular Labral Repair	
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Extracapsular Repair		······································
Medial Cobateral Ligament Repair	Knee .	
Indications - Tenodesis Reconstruction   Patellar ligament Tendon Repair   Joint Claysule Closure   Patellar ligament Tendon Repair   Vastus Medial Soliquous Austence Advancement   Indications - Interference Screws are indicated for the restatchment of lagament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee.   Indications - Indications - Interference Screws are indicated for the restatchment of lagament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee.   Indications - Tenodesis Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.   The Tenodesis Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.   The Tenodesis Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.   The Tenodesis Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.   The Tenodesis Screws are intended to be used for fixation of tissue, including ligament reconstructions   Indications - Tendon to Bone. See below for specific indications.   The Tenodesis Shoulder   Indications - Tendon transfers   Indications - Tendon transfers in the following procedures:   Shoulder   Indications - Tendon transfers in the following procedures:   Indications - Tendon transfers in the following	Extracapsular Repair	
Dostroir Oblique Ligament Repair   Dostroir Oblique Means (Courte   Distribus 18 and Tenodesis Reconstruction   Patellar Ligament Tendon Repair   Vastus Mediáš Obliques Muscle Advancement   Indications -Interference Screws are indicated for the reattachment of ligament, Lendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 23 mm or less are also Intended for the use in the following procedures:  All screws with a diameter of 9 mm or less and a length of 23 mm or less are also Intended for the use in the following procedures:  An Expairs   PCL repairs   Debrigation   Debrigat	Medial Collateral Ligament Repair	
Dinit Closure   Closure   Dinit Closure   Dinit Patch Repair   Vastus Medis Obliquis Muscle Advancement   Indications —Interference Screws are indicated for the restatchment of lagament, tendon, soft tissue, or bone to bone during crudate ligament reconstruction surgeries of the knee.   All creams with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   All creams with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   All creams with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   All creams with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   All closures are also intended for the use in the following procedures:   Shoulder   Closures are also intended for the use in the following procedures:   Shoulder   Closures are also intended for the use in the following procedures:   Shoulder   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in the following procedures:   Closures are also intended for the use in t	☐ Lateral Collateral Ligament Repair	
Biotibial Band Tenodesis Reconstruction   Parellar Irgament/Tendon Repair   Vastus Medids Obliquous Muscke Advancement   Indications —Interference Screws are indicated for the restractment of ligament, tendon, soft tissue, or bone to bone during crudate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less are also intended for the use in the following procedures:	Posterior Oblique Igament Repair	
Patellar Ligament/Tendon Repair	☐ Joint Capsule Closure	
Vastus Medids Obliquus Musche Advancement   IndicationsInterference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during crudical ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less are also intended for the use in the following procedures:	☐ Biotibial Band Tenodesis Reconstruction	
Indications —interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:    Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less and a length of 23 mm or less and a length of 23 mm or less and a length of 24 mm or less and a length of 25 mm or less and a length of 25 mm or less are length of 25 mm or less and a length of 25 mm or less and	Patellar Ligament/Tendon Repair	
Indications —interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:    Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:   Mais crews with a diameter of 3 mm or less and a length of 23 mm or less and a length of 23 mm or less and a length of 23 mm or less and a length of 24 mm or less and a length of 25 mm or less and a length of 25 mm or less are length of 25 mm or less and a length of 25 mm or less and	☐ Vastus Media's Obliquus Muscle Advancement	
The Titan Interference Screws are indicated for the restratchment of ligament, tendon, soft tissue, or bone to bone to bone during cruciate ligament reconstruction surgeries of the knee.  All screws with a diameter of 3 mm or less are also intended for the use in the following procedures:  Knee    ALtepairs   ALTEPAI		Indications –Tenodesis Screws
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bone/tendon to bone. See below for specific indications.  All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:  Knee    ALtepairs   ALtepairs   Patraapsular repairs     Etracapsular repairs   Detracapsular repairs     Etracapsular repairs   Detracapsular repairs     Detracapsular stabilization   Denterior blouder instability     O lateral collateral ligament   O Posterior oblique ligament   O Posterior   O Posterior oblique ligament   O Posterior oblique ligament   O Posterior		
All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:  Knee   ACL repairs   ACL repairs   Capsular stabilization   Cap		• • • • • • • • • • • • • • • • • • •
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See below for specific indications.  Knee  ACLrepairs  Chropairs  Chropairs  Medial collateral ligament  O Posterior oblique ligament  O Posterior oblique ligament  O Posterior oblique ligament  O Posterior oblique ligament  O Patellar realignment and tendon repairs  O Patellar realignment and tendon repairs  O Patellar realignment and tendon repairs  D Patellar realignment and tendon repairs  O Lateral collateral ligament  O Patellar realignment and tendon repairs  D Patellar realignment and tendon repairs  D Patellar realignment and tendon repairs  D Eloid repairs  Rotar croft carpuloter instability  O SLAP lesion repairs  Capsular stabilization  D Bankart repair  D Rotar repair  D Rotar repair  D Eloid repairs  Rotar croft tear repairs  D Eloid repairs  D Eloid repairs  Medial or lateral instability repairs/reconstructions  Medial or lateral instability repairs/reconstructions  D Eloid repairs  D Eloid repairs  D Eloid repairs  Medial collateral ligament repair  D Eloid repairs  D Eloid r	<del>-</del>	•
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o Medial collateral ligament o Posterior oblique ligament o Posterior oblique ligament O Patellar realignment and tendon repairs O Vastus medials oliquous advancement   Dioribial band tenodesis Shoulder   Dioribial band tenodesis Shoulder   Capsular stabilization O Bankart repair O Capsular stabilization O Bankart repairs O Capsular stabilization O Bankart repairs O Capsular stabilization O SLAP lesion repairs O Capsular stabilization O Bankart repair O Capsular stabilization O SLAP lesion repairs O Capsular stabilization O Bankart repair O Capsular stabilization O Bankart repairs O Capsular shift of capsulolabral reconstructions O Capsular shift of capsulolabral reconstruction O Capsular shift of capsulolabral reconstructions O Capsular shift of capsulolabral reconstruction O Capsular shift of capsulolabral reconstructions O Capsular shift of cap		•
o Lateral collateral ligament o Posterior oblique ligament Patellar realignment and tendon repairs o Vastus medialis oliquous advancement   Deltoid repairs     Deltoid repair     Delt		•
O Posterior oblique ligament	_	<u> </u>
Patellar realignment and tendon repairs   Vastus medialis oliquous advancement	<u> </u>	·
Rotator cuff lear repairs   Rotator cuff lear lear lear lear cuff lear lear lear lear lear repair   Rotator cuff lear lear repairs   Rotator cuff lear lear repairs   Rotator cuff lear lear repair   Rotator cuff lear repairs   Rotator cuff lear lear repairs   Rotator cuff lear repairs   Rotator cuff lear repairs   Rotator cuff lear repairs   Rotator cuff lear repair   Rotator cuff lear repair   Rotator cuff lear repair   Rotator cuff lear repair	· =	•
Biceps tenodesis   Biceps teno		<b>—</b>
Shoulder    Capsular stabilization	•	1 <del></del>
Capsular stabilization   Capsular stabilization   Capsular stabilization   Capsular stabilization   Capsular stabilization   Capsular shift of capsulolabral reconstructions   Capsular shift of capsulolabral ligament repairs   Capsular shift of capsulolabral ligament reconstructions   Capsular shift of cap		····•
Medial stabilization   Lateral stability   StaP lesion repairs   Medial stabilization   Lateral stab		
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O SLAP lesion repairs O Capsular shift of capsulotabral reconstructions   Acromicolavicular separation repairs   Deltoid repairs   Rotaor cuff tear repairs   Biceps tendesis   Foot and Ankle   Halbux valgus repairs   Medial or lateral instability repairs/reconstructions   Achilles tendon repairs/reconstructions   Medial or lateral instability repairs/reconstructions   Medial or lateral instability repairs/reconstructions   Medial or lateral ligament/tendon repairs/reconstructions   Metatarsal ligament/tendon repairs/reconstructions   Metatarsal ligament/tendon repairs/reconstructions   Metatarsal ligament/tendon repairs/reconstructions   Metatarsal ligament Repair   Patellar Tendon Repair   Medial Oblateral ligament Repair   Lateral Collateral ligament Repair   Posterior Oblique ligament Repair   Illiotibial Band Tendesis   Posterior Oruciate ligament Repair   Illiotibial Band Tendesis   Illiotibial Band Tendesis   Posterior Oruciate ligament Repair	•	T
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Metatarsal ligament repair   Deltoid repairs   Bunionectomy   Pexor Hullucis Longus for Achilles Tendon reconstruction   Tendon transfers in the foot and ankle   Medial or lateral instability repairs/reconstructions   Metatarsal ligament Repair   Patellar Tendon Repair   Patellar Tendon Repair   Posterior Oblique Ligament Repair   Bunionectomy   Pexor Hullucis Longus   Posterior Oblique Ligament Repair   Posterior Obliqu	- ·	
Deltoid repairs	,	I =
Rotar cuff tear repairs	-	1 <del>.</del>
Biceps tendesis   Tendon transfers in the foot and ankle   Knee   Hallux valgus repairs   Medial or lateral instability repairs/reconstructions   Medial or lateral instability repairs/reconstructions   Medial or lateral ligament Repair   Hallux valgus repairs/reconstructions   Medial or lateral ligament Repair   Patellar Tendon Repair   Patellar Tendon Repair   Posterior Oblique Ligament Repair   Posterior Oblique Ligament Repair   Posterior Ouciate Ligament Repair   Posterior Ouciate Ligament Repair   Elbow   Posterior Ouciate Ligament Repair   Elbow   Biceps tendon reattachment   Ulnar or radial collateral ligament reconstruction   Wrist and Hand   Scapholunae Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Carpometakarpal joint arthroplasty (basal thumb joint arthroplasty)   Carpal Ligament Reconstructions and repairs   Tendon transfer in the hand/wrist   Lateral Epicondylitis repair   AND/OR   Cover-The-Counter Use   Calleral Collateral	<del>-</del>	
Medial Or lateral instability repairs/reconstructions   Medial or lateral instability repairs/reconstructions   Medial Or lateral instability repairs/reconstructions   Medial Collateral Ligament Repair   Lateral Collateral Ligament Repair   Patellar Tendon Repair   Posterior Oblique Ligament Repair   Medial Collateral Ligament Repair   Medial Collateral Ligament Repair   Posterior Oblique Ligament Repair   Medial Collateral Ligament Repair   Medial Collate		_ · · · · · · · · · · · · · · · · · · ·
Hallux valgus repairs   Medial Or lateral ligament Repair   Lateral Collateral Ligament Repair   Lateral Collateral Ligament Repair   Lateral Collateral Ligament Repair   Patellar Tendon Repair   Posterior Oblique Ligament Repair   Illiotibial Bandon tendesis   Posterior Oruciate Ligament Repair   Illiotibial Bandon reattachment   Illiot	<del></del>	
Medial or lateral instability repairs/reconstructions   Achilles tendon repairs/reconstructions   Midfoot reconstructions   Metatarsal ligament/tendon repairs/reconstructons   Posterior Oblique Ligament Repair   Posterior Oblique Ligament Repair   Distribuial Band Tendoesis   Posterior Cruciate Ligament Repair   Distribuial Ba	Foot and Ankle	
Achilles tendon repairs/reconstructions   Metatarsal ligament/tendon repairs/reconstructons   Metatarsal ligament/tendon repairs/reconstructons   Bunionectomy	☐ Hallux valgus repairs	
Midfoot reconstructions   Posterior Oblique Ligament Repair   Midfoot reconstruction   Midfoot re	Medial or lateral instability repairs/reconstructions	1 · · · · · · · · · · · · · · · · · · ·
Metatarsal ligament/tendon repairs/reconstructions   Bunionectomy   Flexor Hullucis Longus   Posterior Cruciate Ligament Repair   Elbow   Biceps tendon reattachment   Ulnar or radial collateral ligament reconstruction   Ulnar or radial collateral ligament reconstruction   Ulnar Collateral Ligament Reconstruction   Carpometakarpal joint arthroplasty (basal thumb joint arthroplasty)   Carpal Ligament Reconstructions and repairs   Tendon transfer in the hand/wrist   Lateral Epicondylitis repair   Lateral Epicondylitis repair   Lateral Epicondylitis repair   AND/OR   Over-The-Counter Use   Lateral Epicondylitis repair   Carpometakarpal Subpart C)	Achilles tendon repairs/reconstructions	<u> </u>
Bunionectomy   Posterior Oruciate Ligament Repair   Posterior Oruciate Ligament Reconstruction   Posterior Oruci	Midfoot reconstructions	
Flexor Hullucis Longus   Biceps tendon reattachment   Ulnar or radial collateral ligament reconstruction   Ulnar or radial collateral ligament reconstruction   Ulnar or radial collateral ligament reconstruction   Ulnar Collateral Ligament Reconstruction   Ulnar Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty)   Carpal Ligament Reconstructions and repairs   Tendon transfer in the hand/wrist   Lateral Epicondylitis repair      Prescription Use	☐ Metatarsal ligament/tendon repairs/reconstructors	
Tendon transfers   Biceps tendon reattachment   Ulnar or radial collateral ligament reconstruction   Wrist and Hand   Ulnar or radial collateral ligament reconstruction   Scapholunate ligament reconstruction   Inar Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Carponal Ligament Reconstruction   Carponal Ligament Reconstruction   Inar Collateral Ligament Reconstruction   Radial Collateral Ligament Reconstruction   Carponal Ligament Reconstructions and repairs   Inar Collateral Ligament Reconstruction   Carponal Ligament Reconstructions and repairs   Inar Collateral Ligament Reconstruction   Carponal Ligament Reconstructions and repairs   Inar Collateral Ligament Reconstruction   Carponal Ligament Reconstruction   Carponal Ligament Reconstruction   Carponal Ligament Reconstructions and repairs   Inar Collateral Ligament Reconstruction   Carponal Ligament Reconstruction	☐ Bunionectomy	<u> </u>
Elbow, Wrist, and Hand    Dinar or radial collateral ligament reconstruction   Ulnar or radial collateral ligament reconstructions   Lateral epicondylitis repair   Scapholunate ligament reconstruction   Tendo transfers	☐ Flexor Hullucis Longus	Elbow
Biceps tendon reattachment   Wrist and Hand   Scapholunae Ugament Reconstruction   Inar or radial collateral ligament reconstructions   Inar Collateral Ligament Reconstruction   Radial Collateral	☐ Tendon transfers	☐ Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions    Iateral epicondylitis repair	Elbow, Wrist, and Hand	Ulnar or radial collateral ligament reconstruction
Interal epicondylitis repair	☐ Biceps tendon reattachment	Wrist and Hand
Lateral epicondylitis repair	Ulnar or radial collateral ligament reconstructions	Scapholunæ Ligament Reconstruction
Scapholinate ligament reconstruction   Radial Collateral Ligament Reconstruction   Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty)   Carpal Ligament Reconstructions and repairs   Tendon transfer in the hand/wrist   Lateral Epicondylitis repair      Prescription Use   Over-The-Counter Use (21 CFR 801 Subpart C)		Ulnar Collateral Ligament Reconstruction
Prescription Usev AND/OR (Part 21 CFR 801 Subpart D)  arthroplasty)    Carpal Ligament Reconstructions and repairs     Tendon transfer in the hand/wrist     Lateral Epicondylitis repair    Over-The-Counter Use (21 CFR 801 Subpart C)	Scapholunate ligament reconstruction	☐ Radial Collateral Ligament Reconstruction
Prescription Usev AND/OR (Part 21 CFR 801 Subpart D)    Carpal Ligament Reconstructions and repairs   Tendon transfer in the hand/wrist   Tendon transfer in the hand/w	☐ Tendo transfers	Carpometalcarpal joint arthroplasty (basal thumb joint
Prescription Usev AND/OR Over-The-Counter Use (21 CFR 801 Subpart D)		
Prescription Usev AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)		
Prescription Usev AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)		
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)		☐ Lateral Epicondylitis repair
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)		•
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)	Prescription UseV	
	(Part 21 CFR 801 Subpart D)	" (21 CFR 801 Subpart C)
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley Ph.D.

Division of Onthopedic Devices